

Premarket Notification [510(k)] Summary

JUN 26 2001

[as required by section 807.92(a)]

K 010 937

Name of Device	Syringe Infusion Pumps SEP-10S PLUS and SP-12S PRO
Common or usual name	Syringe Infusion Pumps
Classification name	Infusion pumps
Product code	FRN
Submitter	Viltechmeda Ltd. 125 Kalvariju St. LT-2042, Vilnius, Lithuania
contact person	Dr. Koby Ben-Barak / Benny Arazy Arazy Group e-mail: koby@arazygroup.com benny@arazygroup.com fax: 972-4-994-4224 tel: 972-4-994-0337, 972-4-994-7880
Predicate Devices:	1) Profusor Compact , manufactured by B/BRAUN Medical Inc. 2) 3400 Infusion pump , manufactured by Graseby Medical Ltd.

DEVICE DESCRIPTION

Syringe infusion pumps are widely used in various clinical and research institutions. Infusion pumps are designed to provide a constant flow of liquids for prolonged periods of time. These are required in many clinical settings. The most widely used utilization of such pumps is the administration of prescribed and accurate dosages of drugs into patients' veins.

The two infusion pumps herein submitted, employ syringes as the drug-containing vessels. By means of syringe type and volume, and by means of flow rate determination, accurate levels of drugs can be infused for predetermined periods of time. The solutions administered may contain various types of medicines, drugs, anaesthetics, antibiotics, salts, chemotherapeutic drugs, and the like. The syringes are not intended to administer blood, or blood products. The solutions to be administered are filled by the personnel, and are contained within syringes of predetermined sizes.

The two syringe pumps are programmable, allowing the users to determine, with great accuracy, the exact flow rate and dosage of fluids or drugs administered. The two syringe infusion pumps are essentially identical. The only major difference between the two pumps lies in the fact that the SP-12S PRO is a more sophisticated model, allowing several more programming modes. The most significant of those is the ability to take into account the patient's weight (0.4-200kg), drug concentration (1mcg/ml-999mg/ml), or drug mass (1mcg-99, 999mg), and infusion rate in mass units (0.1-999mcg/kg/min).

Extensive preclinical tests have validated that the two infusion pumps provide a constant and accurate flow of liquids under a wide variety of pressure ranges. Mechanical, electromagnetic and software validation tests have also demonstrated that the two pumps are safe and reliable to use for both the patients as well as the treating personnel.

INTENDED USE

The two syringe pumps are intended for precise and continuous dosing of solutions injected by means of disposable syringes.

SUBSTANTIAL EQUIVALENCE

The SEP-10S PLUS and SP-12S PRO Syringe Infusion Pumps have been compared and found substantially equivalent to two legally marketed syringe infusion pumps: - **Profusor Compact**, manufactured by B/BRAUN (K983005), and **3400 Infusion Pump**, manufactured by Graseby Medical Ltd. (K931318).

The two infusion pumps and the two predicate devices all have the same intended use. All pumps are designed to accommodate a wide range of syringe types, so as to enable the user to employ the pumps in clinical situations where small volumes and/or dosages are required, as well as where large volumes and dosages should be administered.

Both syringe infusion pumps and the two predicate devices employ essentially identical principle of operation. They all use the swivel-drive pumping mechanism, which converts the rotating movement of the electrical engine to a continuous horizontal progression of a rod, which in turn pushes the piston of the liquid-filled syringe. The use of syringes of various sizes, as well as the monitoring of the number of engines

rotations bring about a constant flow of solutions, at a predetermined rate, from the syringe into the tubing.

All four pumps are intended to provide constant and steady flow of fluids into the patient's veins, through syringes and tubing. The pumps do not come in direct contact with the fluids or the patient. All four pumps are designed to maintain liquid flow rate as low as 0.1ml/hr, up to several hundreds mls/hr, depending on the syringes used.

Being conscious of the fact that failures, either due to mechanical or electrical failures, or personnel misuse, cannot be totally prevented, the two pumps, as well as the two predicate devices are equipped with various ALARM and safety modes. These alarm warnings, by form of highly visible signals, are designed to alert the treating personnel to the failure, and initiate corrective measures. Comparison of the alarm modes of the two pumps and those of the two predicate devices reveals great similarities. There are minor differences between them (as well as between the two predicate devices), but these relate to subtle variations, which have no bearing upon the pumps' safety. Also, for extra safety, all four pumps are equipped with an internal battery, which is activated as soon as the external power is disrupted. The battery maintains a steady fluid flow for an extended period of time, while the alert signal is displayed.

CONCLUSIONS

The SEP-10S PLUS and SP-12S PRO syringe infusion pumps have the same intended use, principle of operation, and technological characteristics as the two predicate devices, the B/BRAUN's - **Profusor Compact**, and the Graseby's **3400 Infusion Pump**.

The four pumps are designed to alert the user in case such malfunction occurs. Comparison of the safety and alarm function clearly demonstrates that all pumps, the two proposed, as well as the two predicate pumps, offer very similar array of alert signals. There are minor differences between the alarm functions of the two proposed pumps and each of the two predicate pumps. However, these minor differences do not raise any new type of question of safety and effectiveness.

In conclusion, the SEP-10Plus and the SP-12PRO syringe infusion pumps were found to be substantially equivalent to the two predicate devices in their intended use, technical characteristics, and their safety and alarm features.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2001

Mr. Koby Ben-Barak
Arazy Group
Mitzpe Aviv Industrial Park 13
M.P. Misgav,
ISRAEL

Re: K010937
Trade/Device Name: Syringe Infusion Pumps:
SEP-10S PLUS and SP-12S PRO
Regulation Number: 880.5725
Regulatory Class: II
Product Code: FRN
Dated: March 14, 2001
Received: March 29, 2001

Dear Mr. Barak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

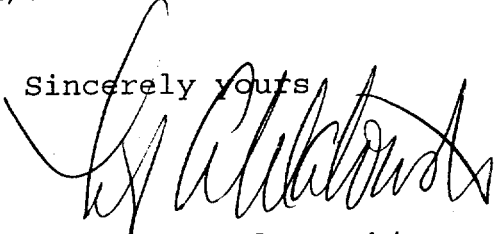
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR.807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement


510(k) Number: K010937

Device Name: Syringe Infusion Pumps:
SEP-10S PLUS and SP-12S PRO

Indications for Use: The two syringe pumps are intended for precise and continuous dosing of solutions injected by means of disposable syringes.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010937

Prescription Use: X
(Per 21C.F.R. 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)